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Mind the gap: Investigating the conditions and processes involved in influencing the development of medical device regulation in India**Dinar Kale**

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Mind the gap: Investigating the role of collective action in the evolution of medical device regulation in India**ABSTRACT**

Using the Indian medical device sector as a case study, this research examines the evolution of regulatory frameworks by analysing the conditions and processes through which regulatory environments for a technology-based industry come about. It also attempts to unpack the complex relationships between industrial capabilities in healthcare technology and human health, and the role of regulation in facilitating more inclusive healthcare and development in emerging countries. In doing so, the paper explains the ways in which an absence of collective action can severely inhibit the development of appropriate technological regulation and industry growth, particularly in the context of developing countries. It shows that contestation, conflict and coalitions as a key mechanism through which different stakeholders influence, enable and/or disable institutional change. These findings have significant implications for other developing countries which are struggling with the development of healthcare technology regulatory policy that is appropriate to local societal context and needs.

Keywords: healthcare, collective action, medical devices, India, regulation, technological capabilities

1.0 Introduction

The healthcare sector is witnessing an increasingly expanding domain of innovative biomedical technologies, promoted as radically changing the character of medicine, healthcare and human health itself (Sorenson, 2015). These developments pose significant challenges for law, regulation and governance. The life science industries and biomedical innovation are a significant part of government agendas and a major subject of public concern about risks and benefits (Faulkner, 2012). Regulation policy has emerged as an important pillar of technology policy and an integral part of government intervention to stimulate and control innovation. Regulatory policy in healthcare sector adds a new challenge as it straddles the boundaries of several disciplines and requires theoretical, analytical and conceptual insights from other disciplines complementing insights from law and political science (Altenstetter, 2014). From an innovation systems perspective, innovation and regulation are path dependent processes influenced by state and non-state actors (Nelson, 2002). Here regulation is viewed as ‘a process of involving sustained an attempt to control, order or influence the behaviours of actors so as to produce identified outcomes’ (Harmon and Kale, 2015). For the healthcare sector, Altenstetter (2014:363) argues that ‘how and to what extent each regulatory framework has evolved over time, and what triggered these institutional changes, remain at the centre of political, social and scientific forces that together shape national regulators’ responses to new challenges and thus relations between technology and society.

Unsurprisingly, the form, scope, and stringency of regulation have been and continues to be, much discussed, with governments frequently struggling to devise appropriate regulations that balance all stakeholders’ interests. Studies on healthcare regulation clearly show its impact on shaping innovation trajectories, influencing industry structure and determining firm-level technology strategies (Faulkner, 2009). In developing countries, regulation is strongly linked with preventing counterfeit products, and the appropriateness and enforcement capacity of local governments (Harmon and Kale, 2015). Despite the ever-expanding knowledge base, Sorenson (2012) argues that more research is needed to assess factors and processes influencing the evolution of regulatory frameworks in different contexts and their impact on local manufacturers and health systems.

Similar to pharmaceuticals and vaccines, medical devices are essential for patient care in operating theatres, at the bedside, even before a patient is admitted to a hospital, or after discharge. According to the WHO (2012) “medical devices” includes everything from highly sophisticated computerised medical equipment down to simple wooden tongue depressors. There has been extensive research that explored the evolution of regulation and its impact on pharmaceutical and biotechnology industries but regulation in medical device industries has remained a neglected area of research in social science and health policy studies (Altenstetter and Premanand, 2010) and only a few studies have been published focusing on medical device regulation (Altenstetter 2003; Altenstetter 2008; Altenstetter 2012; Altenstetter and Permanand 2007; Kramar et al. 2012; Kramar et al. 2013). In developing countries, some research has focused on the issues of diffusion and access of medical devices (WHO, 2012; Kale and Wield, 2019, Nadvi, 1999; Loureiro et al., 2008). Yet, the regulation and development of appropriate medical devices affordable to local population appears under-researched and needs more attention. Building on the work of Altenstetter (2010) and Faulkner (2009), this research tracks the evolution of Indian medical device regulation and analyses its impact on local manufacturers and availability of affordable healthcare, revealing how regulatory institutions evolve in an emerging economic power.

The Indian medical device industry provides an appropriate setting to conduct this research. Over the years, the Indian medical device regulatory framework has oscillated from lack of regulation to inappropriate regulation to coherent regulation. Further, compared to the Indian pharmaceutical and biotechnology industries, medical device industry has struggled to make a significant impact on local healthcare provision. Employing qualitative methodology this research explores how regulatory institutions evolve, what factors trigger that change and examines the impact of these changes on local firms and affordable healthcare.

This paper shows that evolution of Indian medical device regulation was profoundly and negatively shaped by limited understanding of the medical device industry among policymakers; by policy fragmentation within government departments; and an absence of institutional linkages between industry and government. It further reveals that the expertise mobilised to reform the regulatory and governance system was disconnected from local contexts, giving rise to a healthcare technology and regulatory policy detrimental both to local firms and consumers but beneficial to multinational firms, counterfeit manufacturers and spurious distributors, with negative consequences for the local health systems and industrial capacities.

This paper is structured as follows. Section two discusses drivers and significance of regulation in healthcare sectors, highlighting the key issues that have shaped medical device regulation in both advanced and developing countries. Section three explains the theoretical framework while section 4 elaborates on our research methodology. Section five describes the evolution of regulation of the Indian medical device sector in three different phases. Section six discusses the conditions and processes influencing the development of Indian medical device regulation. Section seven offers some policy implications and presents the main conclusions drawn.

2.0 Regulation in healthcare: Evolution and impact

Over the past several decades, the regulation of healthcare technologies has become more vital as well as highly contentious. From an innovation systems perspective, the nation state is seen as the central actor in setting regulation norms. The global nature of industry activity means that state-level governance must engage with international and global forms of governance, public and private, in its search for efficient modes of improving society's access to innovation (Faulkner, 2012). As such, the policy environment within which decision-making is exercised is spread among actors with varying perspectives and objectives. That said, some common objectives among healthcare stakeholders are held: to ensure safety, efficacy and quality of products for mass consumption, to create a set of incentives and constraints to influence behaviour of economic agents with the assumption that these rules stimulate development of safe and effective innovative products, and to develop sustainable institutional modes that have enough flexibility to accommodate the evolution of a particular set of technologies (Harmon and Kale, 2015).

These innovative healthcare technologies need regulatory approvals to enter markets and that has significant implications for product life cycles, R&D costs and competitiveness (Henderson et al., 1998). Building on this, Tait et al., (2007) and Altenstetter (2014) point out that in the healthcare industries, regulation has a strong impact on market behaviour, firm strategies, the dynamism of the sector and patient access to new technologies. In this context, Sorenson (2014) points out that regulation inevitability brings together public and private interests in a process where there are potential winners and losers and the perception of the outcome is highly contingent on each party's point of view. For example, regulators often

face political pressures and stakeholder resistance, leading to problems with compliance or hastened approval processes that may introduce later safety risks or actualised injury (Sorenson, 2015). As a result, studies on regulation and technological innovation in the healthcare sector are increasingly focused on the boundaries of regulation and limits to governance in this regard (Lyall et al., 2009). Previous studies on regulatory changes in healthcare industries have engaged with issues such as how is regulation constructed under conditions of scientific and technological uncertainty and ‘inherited’ regulatory pathways (Stokes, 2012), and how far does the operation of the regulatory regime encourage and depend on the interaction between regulators and regulated? (Wilson-Kovacs & Hauskeller, 2012). In this context, Faulkner (2012:358) suggests that ‘a key issue in assessing regulation is the working of the ‘match’ (or otherwise) between technology/product/sector boundaries and the configuration of regulatory institution and guidance designed to regulate the field, noted in the concept of regulatory connection’. However, knowledge of factors and processes influencing the evolution of regulatory policy in different technological and societal contexts and their impact on local entrepreneurship and capability development is very limited.

2.1 Medical device regulation: a neglected but critical element of healthcare policy

The medical device industry (MDI) is a semi-regulated sector globally and regulatory environments have significant implications for industry's performance. Medical devices occupy a central role in the provision of affordable healthcare and to date, medical device regulation has remained a neglected area in social science and health policy studies (Altenstetter, 2014, Sorenson & Drummond, 2013). Some studies have looked at medical device regulation in advanced regions (Basu & Hassenplug 2012; Kramer et al. 2012), emphasising the challenges with current regulation systems (Cohen & Billingley 2011; Freemantle 2011; Hines et al. 2010). However, in the resource constraint environment of developing countries, the evolution of medical device regulation and its linkage with capabilities of local manufactures and health systems have been generally poorly understood.

The medical devices sector includes a huge variety of products ranging from medical gloves, bandages to dialysis equipment, baby incubators, and heart valves. There are more than 10,000 major categories of medical devices and diagnostics worldwide (WHO, 2010) including any instrument, implant, machine, intended to be used, alone or in combination, for one or more specific purposes such as diagnosis, prevention, monitoring, treatment, or alleviation of disease (Shah and Goyal, 2008). The global medical device market was valued at \$164 billion US in 2010, growing at a compound annual growth rate (CAGR) of 6% since 2000 (WHO, 2012). The USA constitute 41% of the world's total market, followed by Japan (10%), Germany (8%) and France (4%) (WHO, 2010). The significance of intellectual property rights as incentives to innovation is less important in the medical device industry. According to Kanh (1991), patent appears to be of relatively less important in many segments of the device industry as it is possible to design a medical device for a specific application in several different ways. Medical devices play an increasingly critical role in clinical practice, improving patients' health and quality of life. Yet, Altensatter (2010) argues that the regulation of medical technologies is one of the most neglected areas in the National Innovation Systems (NIS) literature, Development Studies and Science and Technology Studies (STS). The significant growth of the medical device industry and consequent increased development and availability of sophisticated, costly devices creates a need for more research.

Regulatory systems for medical devices have an important role in promoting technological innovation, facilitating market access and ensuring the protection of public health; regulation

is as much about risks as it is about markets and companies (Altensetter, 2012). The medical device industry has witnessed significant growth US\$85 billion in 2001 to US\$146 billion in 2009 (Kruger & Kruger 2012), revealing increased scale and scope of use in patient care and markets across the world. New market entrants are a key factor in driving this large growth and Sorenson (2015) suggests that along with the higher number of new devices, underlying technologies and knowledge have become more complex. Medical technologies involve a combination of knowledge bases from diverse disciplines such as design, material engineering, medical biology, pharmacology and physiology and primarily incremental type, resulting from clinician insights rather than laboratory exploration (Von Hippel, 1988), creating distinctive challenges for devising optimal regulation. This makes the regulation of medical devices a vast and rapidly evolving field that is often complicated by legal technicalities.

In advanced countries, the early models for medical device regulation were based on drug regulation before splitting off from it. The inherent differences between drugs and devices make uncritical application of drug regulatory model for device governance significantly challenging (see Table 1).

Table 1 Differences between medical devices and drugs (Global Medical Technology Alliance, 2015)

Medical devices	In Vitro Diagnostic Medical Devices	Pharmaceuticals
In vivo and/or ex vivo use	<i>In vitro</i> use	<i>In vivo</i> use
Diagnostic or therapeutic intended uses	Diagnostic intended use	Therapeutic intended use
Outcomes of use often depend directly on skill or experience of user	Outcomes generally not dependent on skill or experience of user	Outcomes generally not dependent on skill or experience of user

Active Components Generally based on mechanical, electrical, and materials engineering. Many medical devices incorporate and are driven by software	IVD components have no therapeutic effect – only used for diagnosis. Key components are those essential for detection of the analyte of interest. Biological core reagents (e.g. antibodies) Performance of tests (e.g. sensitivity, specificity) depends on design of test, geographic variations of the infective agent, populations, and the setting of use Variable batch sizes for a given reagent, individual batches of the same reagent may use different starting materials. Stability varies between products and may vary between batches. Generally stored at 4°-8°C Generally short shelf lives (< 12 months)	Based on pharmacology and chemistry; now encompassing biotechnology, genetic engineering, etc. Pharmacologic properties and action of active ingredients are known, based on pre-clinical and clinical studies Standardized batch sizes, manufacturing processes and starting materials. Products stable. Generally stored at room temperature Generally long shelf lives
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The performance of medical device depends not only on the device itself but also how it is used. Significantly, the intended primary mode of action of a medical device on the human body, in contrast to that of medicinal products, is not metabolic, immunological, or pharmacological, requiring a different set of regulations compared to pharma-biotech products. These differences have significant all three keys phases product lifecycle that are covered by regulatory controls: ‘(i) pre-market controls (the regulatory requirements for getting products approved and licensed for sale on the market (ii) post-market controls (understood as manufacturers’ obligation to operate a system for obtaining feedback from the marketplace) and (iii) medical vigilance (understood as the obligation to report serious adverse health incidents to the competent authority) (Altenstetter & Permanand, 2007:11) and that led to evolution of a legally autonomous medical device regulatory framework starting with the United States in 1976, which was gradually, strengthen with four major amendments in 1992, 1997, 2002 and 2007. This strong link between drug regulations with medical device regulation indicates path-dependent developments and interpretations are at the core of each medical device regulatory framework.

Medical devices around the world are classified based on their safety requirements and several criteria are considered to evaluate the potential risk: degree of invasiveness, duration of contact, affected body system and local versus systemic effects. The extent of scrutiny of medical devices is based on the risk class attached to their use. Low-risk devices are assessed by manufacturers while in case of high-risk devices significant evidence is needed for their evaluation. This evidence includes criteria on efficacy and safety associated with the device however in case of devices clinical effectiveness (when a device produces the effect intended by the manufacturer relative to the medical conditions) is challenging to prove. This process involves extensive pre-and post-market studies. All approved devices have to undergo review and assessment to ascertain their benefits and risks to public health before being marketed on the health care system. The different comparative studies of the medical device regulation in advanced regions show that the United States, the Europe and Japan have adopted different

regulatory processes, governance structure and evidence requirement for approval of devices (Sorenson & Drummond, 2014). Despite these differences the regulatory framework in these regions share same objectives: to ensure a level playing field for global trade and access to liberalised markets, to enhance human well-being, and to secure health promotion (see Kramar et al., 2013; Lobmayr; 2010; Kahan, 2009; Sorenson & Drummond, 2014; Chai, 2000, Altenstetter, 2012). This research reveals the emergence of innovative technologies, a globally operating industry and locally delivered healthcare as key drivers of medical device regulation (Altenstetter, 2014). More significantly it identifies the strong government-industry linkages and global harmonisation agreements as key processes that drive and shape the medical device regulations in advanced countries

In case of developing countries, medical device regulation has remained a significant challenge for policymakers and industry. According to WHO, (2013), 53% of low-income countries (18 out of 34 low-income economies) and 45% countries in Africa have no regulatory authority. Evidence suggests that a lack of knowledge concerning the medical device industry along with lack of resources and capability has resulted in absence of regulation in a significant number of developing countries. For developing countries, this lack of capacity points to significant gaps and disconnections between governments and industry and between local and global knowledge sources.

‘Medical-Industrial Complex’: Key role of government-industry linkages

Effective government-industry relations are identified as essential elements of innovation systems and a significant contributor to the shaping of regulations in the biopharmaceutical industries (Watkins et al., 2015). Focusing on MDI, Nadvi (1999) demonstrates that industry associations not only mobilise collective response to government regulatory policies but also help the policy implementation process among firms. Analysing MDI regulation processes in advanced countries, Altenstetter (2012) notes that two teams of players are typically engaged in bargaining, negotiating and solving conflicts and regulatory issues in the international, regional, and national arena. One team consists of the United States-led medical-technology industry (Kruger 2005) and global device companies which, at least in the high-risk medical device markets, have come to dominate and are the most successful in terms of approved medical device innovations, profitability, and sales (Lobmayr 2011). The influence of device companies is reinforced by the relevant industry associations: AdvaMed in the United States; Eucomed and other EU-based trade associations in the EU; and the Japanese Federation of Medical Device Associations (JFMDA). At the helm of the other team of the regulatory process are the respective regulatory authorities such as USFDA, PDMA (Pharmaceutical and Medical Device Agency, Japan) and EMA. These two teams seek out scientific expertise occasionally in-house but more frequently from out-of-house professional/scientific and ‘industry experts’ who serve on different advisory committees and provide the scientific input to the regulatory mission.

Hancher & Moran (1989) suggest that these three constituents represent the ‘medical-industrial’ complex of the regulatory space of medical device regulation, indicating the regulation of medical devices is as much as about risks as it is about markets and companies (Altenstetter, 2012). Emphasising significance of industry-government linkages, Tan (2012) reveals that in 2012, owing to pressures from various trade organisations (the Tokyo-based AMDD, the JFMDA, the US-based AdvaMed and the European Business Council), Japan is considering a legislative proposal that would separate medical devices from the Pharmaceutical Affairs Law. This confirms the importance of government-industry linkages in shaping medical device industries regulatory framework adopted in the advanced countries.

Influence of global harmonisation agreements

With their power and status, the EU and the United States have emerged as a strong influence and a driving force for global harmonisation of medical device regulations all over the world. Some developing countries such as Mexico, Brazil have set up regulatory frameworks based on the USFDA and the EU directives. These regulatory regimes contain common structural features that concern with safety and effectiveness of the devices. The advanced countries are also pushing for harmonisation of medical device regulations around the world. For example, to achieve uniformity in the national medical device regularity systems and to improve access to safe and effective medical devices, the Global Harmonisation Task Force (GHTF) was conceived in 1992 by the European Union, the United States, Australia, Japan and Canada. In 2011 GHTF was ceased to exist and replaced by the International Medical Device Regulators Forums (IMDRF) with the aim of “accelerating international device regulatory harmonisation and convergence”. However, this drive for global harmonisation seriously neglects the significant role of nation states and national authorities have in devising a regulatory framework that is suitable for local conditions. In this context this research aims to unpack the conditions, processes and stakeholders involved in the evolution of the medical device regulation in India.

3.0 Theoretical framework: Collective action

It is well established that institutional environment plays a critical role in promoting sectoral growth by creating a social system that either catalyses or hinders emergence and survival of existing and new businesses (Khanna & Palepu, 1997; Gurses and Ozscan, 2015). Within wider aspects of the institutional environment, governance is a widespread term used for describing to the overall coordination and steering of a social system – the processes that maintain integration, direction and oversight (Budd et al., 2006). The ways in which governance is carried out in a particular field or domain such as health, education or food varies hugely and are dependent on the innovation and social system involving a wide range of statutory, judicial, professional and other non-governmental bodies (Lyll et al., 2009). Laws and regulations are identified as critical aspects of governance structures and can critically promote or hinder new products and services through the institutional mechanism they develop (Ruso, 2001). Actual governance arrangements in any particular case are then some mix of these elements and can be achieved in three ways – through hierarchies (such as governments), through markets and through networks (Smith, 2009). In practice, the policy takes shape in and through such governance arrangements, however imperfect.

The dominant understanding of policy suggests that its creation is essentially a formal matter in that policy is a result of a problem being identified, researched and analysed, then a recommendation being put forward, agreed on and implemented (Budd et al., 2006). At the heart of this arrangement is the idea that governments and policymakers are the creators and instigators of policy. The rational policy-making process is attractive to participants in the process, and it is expected by the wider society. But the practical difficulties facing even the well qualified policymakers are enormous. For example, the complexity of the issues involved, and the quantities of information that may be relevant, can potentially overwhelm policymakers. This suggests that policymakers and managers must operate on the basis of ‘bounded rationality’ (Simon, 1957). For example, Kooiman (1993:4) observes that “no single actor, public or private, has all the knowledge and information required to solve complex dynamic and diversified problems; no actor has sufficient overview to make the applications of needed instruments effective”. Policy developed through this linear or policy as

prescription approach could result in wrong policies or policies that run their course, become unviable under the weight of their own inefficiency to change.

This gives rise to an alternative approach, and one that is critical of this linear perspective suggests that policies are the result of learning by doing and the building of consensus over time, so that changes to the way things happen take place in a more organic fashion before eventually becoming routine and legitimate (Mackintosh, 1992). These may involve cross-sector working with actors from public institutions or non-profit agencies. In this context, regulatory policy is ultimately concerned with creating the conditions for an ordered rule and collective action towards technology policy (Lyall, et al., 2009:1). The empirical literature has shown that collective action; purpose collective behaviour is a critical step for gaining socio-political legitimacy (Olson, 1965; King and Soule, 2007) and involves different types occurring at multiple levels (Ostrom, 2009). Collective action can take the form of social movement involving a mobilised network of groups and organisations that try to achieve social change through collective protest (Sine & Lee, 2009) or collaboration among powerful firms (Ozscan & Eisenhardt, 2009). Most common form of collective action is through industry associations, which represents members' interest and lobby for resources, promote agendas and influence policy (Watkins et al., 2016). The studies of the evolution of regulatory policy in the Indian IT industry shows that software and hardware were coupled a very long time with the policy of hardware. Yet de-coupling did happen due to effective collective action by the industry association which engaged the government very selectively for policies that they wanted for the industry (Arora & Athreye, 2002). Emphasising the significance of collective action in the shaping of regulatory policy, Faulkner (2012:356) suggests that state-level governance must engage with international and global stakeholders, public and private, in its search for efficient modes of improving society's access to the products of technological innovation. However, Gurses and Ozcan (2015:1713) point out that 'regarding collective action, our knowledge is limited on how actors can use different types of collective action to influence actors of various types, and whether they tackle them all at once or follow a certain pattern in their approach'.

Overall, our literature review suggests that the form, scope, and stringency of regulation, and the actors who have had a hand in making it, role of collective action has been much discussed and researched in context of advanced countries (Watkins et al., 2016; Harmon & Kale, 2015) and there is a need for empirical historical studies that uncover processes and conditions involved in regulatory changes for healthcare technologies in developing countries. This paper fills that gap by studying the development of Indian medical device regulation.

4.0 Research Methodology

The characteristics of MDI such as nature of innovation, diversity of products and their role in providing effective healthcare makes it a unique industry and creates challenges for comparison with sectors. As a result the research carried out by Altensetter (2014), Faulkner (2009) and Sorenson (2015) who have studied evolution of medical device regulation in different countries have adopted the single case study research methodology. According to Yin (1994) single case methodology is ideal to research a critical and revelatory case as it allows the researcher to analyse phenomenon in depth. Building on that, this research employs Indian medical device industry as a single case study to explore conditions and processes associated with the evolution of India's medical device regulation, its impact on the capabilities of local medical device manufacturers and health delivery systems. This methodology helps to uncover the role of stakeholders and nature of collective action along

with illustrating what did or did not work in the development of Indian medical device regulation. This single case methodology employed here also follows similar studies of evolution of Indian industrial and regulatory policies in other technology industries such as the Information Technology (IT) (Arora & Athreye, 2002) and biotechnology industries (Chaturvedi, 2005).

This research employs historical analysis method to map and understand the significance of key events and role played by different stakeholders in shaping the evolution of Indian medical device regulation. This research covers an extended period, between 1947 till 2018 as this longitudinal approach allows observation of processes and actors associated in shaping regulation over time. We divide the evolution of the Indian medical device regulation into distinct phases based on the nature of regulatory policy that governed the development, production, distribution and marketing of the medical devices in India. This gave rise to the three phases. There was absence of regulation focused on the medical device from 1947 until 2005 and this period of a regulation vacuum is termed as first phase. This significant hiatus is indicative of a major lack of priority given to medical device technologies even as the Indian state moved after independent to build and shape a whole raft of new science, technologies and industries. From 2005 until 2009, instead of developing appropriate regulation to build an important industrial sector, Indian medical devices were regulated using a reaction and inappropriate approach. We characterise this as a second phase of the evolution. The third period of 2009 till 2018 witness the emergence of collective action to developed appropriate rules of governance of medical devices and this period is termed as third phase. For each period, data collection focused on understanding the role and influence of different actors, the key processes of interactions between different actors and the prevailing political and economic context.

Each phase had significant impact on the development of technological capabilities in the Indian firms and accessibility of devices for low-income population. To explore the impact of this evolving medical regulation on technological capability development we categorised our data into two broad themes: impact of regulation on factors lying inside the firm; and those external to the firm. This interaction between evolving regulation and technological capabilities is further explored by focus on Indian medical device firms, which were involved in indigenously developing devices for the Indian markets.

Qualitative primary data collection was carried out in two phases. The first phase involved semi-structured interviews with key, non-firm stakeholders associated with the medical device industry with the aim of understanding key events that shaped the evolution of medical device regulation, role played by different stakeholders and impact of this evolving regulation on access to affordable healthcare. These stakeholders were identified through different sources of secondary data such as newspaper reports, healthcare consultancy reports and business magazine. The participants for the first phase were chosen for their experience and expertise inside the medical, scientific, academic, policy, legislative and regulatory communities. Specifically, interviews were conducted with a leading cardiac surgeon, a biomedical engineer, a major Indian entrepreneur, a healthcare sector journalist, president of the Indian medical device association and a senior government official working with Drug Controller of India (DGCI).

In the second phase, firm-level data collection was carried out involving interviews with key stakeholder associated with Indian medical device firms. In the second phase firm level data collection was carried out and involved interviewing the Head of R&D and the CEO or

Managing Director of the firm. We interviewed senior management in eight Indian medical device firms such as Shushrut-Adler, Achira Labs, TTK Healthcare ltd to grasp the nature and impact of regulatory changes and challenges. Interview questions focused on the status of the Indian medical device industry, regulatory framework, key challenges it raised for the firm and its impact on the development and marketing of the chosen product. Open-ended questions and a relatively unstructured interview schedule were used to encourage participants to speak in their own words about their experiences, observations and opinions. To avoid interviewer bias, the primary data was triangulated with secondary data collected from various sources such as industry journals, industry association publications and annual reports of firms.

In this research a systematic approach to data capture and analysis was taken to ensure a clear 'audit trail' between the data and the conclusions that were distilled (Strauss and Corbin, 2015). The empirical evidence was analysed by using various analytical techniques such as pattern matching (Yin, 1994) and building of analytical tables (Miles and Huberman, 1984). In this research, a strategy of pattern coding is used to identify key events, conditions and processes involved in evolution of medical device regulation. The review of processes and conditions associated with the medical device regulation in advanced countries highlights it as an evolutionary and path dependent process shaped by government-industry linkages and global agreements (Altensetter, 2012). These conditions and processes provide main themes for the pattern coding and formed a key part of the data analysis strategy. In the second level patterns corresponding to impact of evolving regulation on technological capability development and access to medical devices were identified. In both levels the replicating patterns were supplemented by secondary data that was collected from various sources such as industry journals, industry association publications and annual reports of firms.

5.0 The Indian medical device industry

The Indian medical device industry is estimated at the US\$ 4.5 bn in 2012 and growing at the rate of 14% per annum (WHO, 2012). The industry is highly competitive and fragmented; there are more than 800 domestic firms primarily manufacturing low technology products such as disposables/ medical supplies while MNCs dominate the high-end medical devices market. The Indian medical devices industry forms a very small part of the total manufacturing accounting for only 0.2% of all certified facilities (Deloitte, 2010). There are about 14000 medical devices marketed in India and more than 70% of devices are imported from advanced countries such as US, Japan, UK and Germany. According to Deloitte (2010), the key categories of items that are imported into India include imaging equipment, pacemakers, orthopaedic and prosthetic appliances, breathing and respiration apparatus, and dental equipment. Prof. Valiathan highlights the social cost of import dependence,

the imported items are accessed by only 10% of our population. For the MNCs, it is a huge market, Rs 120 million. But we have a 1.2 billion population, if we want to give them access to such items, we need to develop them ourselves.

(Nagarajan, 2013)

Over the years the domestic medical device industry has grappled with issues of quality and struggled to gain trust and market acceptance in the high-technology segment. Kamath (2010) highlights this link between quality issues and growth of the industry,

The words India and medical technology are seldom used in the same sentence. An indigenous medical device industry has been virtually non-existent. Local players,

with some exceptions, have struggled to shed the ‘low-tech, low quality’ tag. For instance, doctors faulted local pacemakers for being too bulky and difficult to implant with leads (that connect the pacemaker to the heart muscle) fracturing easily.
(Kamath, 2010)

The current state of the Indian medical device industry raises questions about the evolution of regulatory policy and its impact on the technological capabilities. The next section presents the evolution of the Indian medical device regulation along with the role of key events, conditions and actors in shaping the current regulatory quagmire. The Indian medical device regulation has evolved through three phases (Table 2).

Table 2 Key milestones in the evolution of Indian medical device regulation

Years	Key events	Phases
1980	Indian government intends to frame medical device regulations but due to lack of understanding and political will no progress is made	Phase I Regulatory vacuum
1990	Indian government liberalises economy and gradually reduces import duty, leads to increasing import of medical devices	
2003	Mashelkar committee publishes report calling for establishment of medical device regulatory division in the Central Drugs Standard Control Organisation (CDSCO)	
2003	ICMR expert committee publishes report calling for central medical device regulatory authority	
2005	60 patients were harmed in hospital due to use of imported stents and high court orders government to set standards for devices	Phase II Regulatory ambiguity
2006	Indian government brings 10 devices under the Drugs and Cosmetics Acts (1940), later 4 more devices added to the list.	
2006	Industry associations starts working with govt to frame appropriate medical device regulation	
2007	Legislation is drafted to develop central medical device regulatory authority, but no progress is made	
2008	Parliamentary committee rules against establishing central authority, object to the clash of views between the Ministry of Health and Family Welfare (MoHFW) and the Department of Science & Technology (DST) on the issue of regulating medical devices, DST issues updated Medical Device Regulatory Bill	
2008	MoHFW & DST proposed two independent bills	
2009	CDSCO establishes autonomous GMP for regulations of medical devices	Phase III Emergence of Regulatory coherence
2013	Amended Drugs and Cosmetic Act is introduced in the parliament	
2018	Launch of Indian medical device regulation	

5.1 Phase I: Era of regulation vacuum (to 2005)

From independence till 2005 there was effectively no quality regulation for medical devices - whether imported or manufactured in the country. Manufacturers of low-tech devices such as thermometers and weighing instruments sought optional certification (ISI marking) from Bureau of Indian Standards (BIS) as a proof of quality but not as a pre-market approval requirement. BIS certified and regulated a few other low technology devices. Due to their limited scope and depth, these standards and procedures were not adequate for high technology devices. The lack of a regulatory environment over this long period indicates the low priority given to medical devices compared to other technological areas and is suggestive of a major gap in science and technology policy towards basic health care.

In the pre-2005 era imported high technology devices approved by the country of origin or by the USFDA were permitted for marketing in India. However, there was no regulatory mechanism to check the certification of the products or product quality. For instance, in 2004 Boston Scientific and Johnson & Johnson withdrew sale of one brand of its cardiac stents worldwide, but no independent information was available in India on how many of these devices may have been used or if any patient had reported any adverse event (Harper, 2003). During this period, the medical device sector stayed under the radar of different industry associations, civil society organisations and remained unrepresented at the government level. Some experts point to the small size of domestic MDI and the low-tech nature of devices as the main reason for the overall neglect of the industry. Dr Valiathan comments,

Pharma was established in India for decades; their R&D picked up momentum after India signed the WTO agreement and patent regime changed. Biotech had novelty and glamour and government set up a department, which promoted it aggressively. Devices suffered from neglect by the medical profession, technologists, industry and government. Poor investment in R&D facilities and absence of 'Medical Device legislation' hampered the growth of the Indian medical device industry.

(Interview data)

In the early 1980s the government did realise the need for medical device regulation but limited understanding of how medical devices work, mechanism of action and criteria for performance measurement hindered further progress. A biomedical engineer with TTK Healthcare comments,

The point was 1980, the year I joined the institute. Prof. Valiathan and I started working on the biomedical device act, but it all got stalled in the end. There was no interest or understanding.

(Interview data)

Post-1990s the economic liberalisation fuelled the growth of the Indian healthcare market and that gave a boost to domestic firms, increased imports of devices and brought additional scrutiny from domestic and international civil society organisations. Taking cognizance of the increasing demand for medical devices and absolute dependence on imports to satisfy that demand, the Indian government significantly reduced import tariffs on medical devices to the range of 15 to 30% and de-licensed imports. This resulted in significant growth in scale, size and scope of imported devices. However, in absence of credible regulation, Harper (2003) argues that in some categories inferior quality products were imported and used for treating low-income populations in India. There were no regulatory guidelines and control on how the

device actually works, its technical specifications and performance. There was little information available on medical devices apart from that provided by firms for marketing purposes. During this period medical devices were sold in India without any monitoring by a regulatory authority or reporting by hospitals. With the exception of few, the majority of domestic firms were comfortable with an absence of regulation and made no strong demand for it. A leading orthopaedic equipment manufacturer points out,

In medical devices multiplicity of technologies that usually brings one solution and thereby validation of devices is a very expensive exercise. In a non-regulated environment like India, you had companies that were not bothered about regulation because there was no regulation and nobody was asking for it. So these companies thrived in giving something cheap even without bothering to take tests if it is right. For example, a representative of MNC went to Ludhiana to source a key product and he found that manufacturing unit was actually a cowshed where they were making this product. That's why the local lobby did not want any restriction.

(Interview data)

This lack of specific regulation for medical devices created significant obstacles for innovative domestic firms involved in indigenous R&D. For example, Sree Chitra Research institute struggled to launch indigenously developed heart valve, as there was no clear authority that was responsible for approval of high-tech medical devices developed locally. In the absence of local regulators, the scientists working on heart valve project decided to get the product tested with the USFDA. A senior engineer associated with heart valve project explains,

In India, there are some islands of excellence in different medical device verticals. What these companies decided that they want to be international in their approach and adopted methodologies that are international. Due to the absence of local regulation, these companies went overseas to USFDA approvals or CE certification. My product was CE certified five years before the local regulation came into practice.

(Interview data)

However, getting international approvals affected completion project further delayed the launch of a product in the market and increased the cost of product development. Acting on a regulatory vacuum, the Indian Council of Medical Research (ICMR) established an expert committee and in 2003 this committee released a report on setting up of the 'Indian Medical Devices Regulatory Authority (IMDRA). This report highlighted the need for regulatory authority, describing the prevalent regulatory situation as,

The R&D efforts can benefit the country only if the final products are made available to the people through Good Manufacturing Practices (GMP) and well-regulated marketing procedures. Unfortunately, no such procedure exists in the country for high-tech devices. It appears that some imported high tech devices, approved by the country of origin or by the FDA, are permitted for marketing in India. As on date, no regulatory mechanisms exist even with the Drug Controller General of India (DCGI) for certification, quality assurance and post-market surveillance of both imported and indigenous medical devices. Obviously, neither any regulatory body has been entrusted with this responsibility nor a new organisation has been created, leaving the quality assurance and regulation of medical device in vacuum. The practice is

followed, as DCGI is to refer the matters related to biomedical devices to ICMR (Indian Council of Medical Research) on a case-to-case basis.

At the same time, another high-profile report on drug regulation also highlighted regulatory vacuum for high-tech medical devices. In 2003, the Indian government set up an expert committee headed by leading scientist Dr Mashelkar to examine drug regulatory issues, including the problems of spurious drugs. Going beyond the remit of drugs, the Mashelkar committee report called for setting up a separate division in Central Drugs Standard Control Organisations (CDSCO) for regulating imported and domestically manufactured medical devices. However, the Indian government took no action on the committee recommendations as it was deemed to be a no-priority area (interview data).

In 2004 neglect of regulatory infrastructure resulted in a serious incident at Jamshedjee Jeejeebhoy (JJ) Hospital in Mumbai. The JJ hospital used unapproved drug-eluting stents on 60 high-risk cardiac patients. Stents were manufactured by Netherland based company and were not approved for use in the EU markets. Taking cognisance of public outcry government shut down the importer and a local company. However, both importer and a local stent company went to court showcasing the absence of regulations. In 2005, the Mumbai High Court discussed the case and ordered the Indian government to set rules and standards for the medical device industry. This started 'a chain of knee-jerk reactions' from the government that resulted in setting up of ambiguous regulation (Interview data).

5.2 Phase II: Era of ambiguous regulation (2005-2009)

This phase is characterised by the emergence of a highly reactive and inappropriate regulatory regime. In March 2006, reacting to the JJ Hospital case and Mumbai high court order the Indian government listed 10 medical devices to be regulated in an amended Drugs and Cosmetics (D&C) Act, 1940. These devices required a license to manufacture, sell and distribute. But no other devices whether imported or manufactured in the country were regulated. An orthopaedic implant manufacturer explains,

At that time there two parallel things that happened. Department of Science and Technology had created what was called Medical Devices Safety Bill, which had recommended creating a separate Medical Device Regulatory Authority, MDRA, as they called it. Prof. Valiathan and group were involved in this. This work was happening when this JJ controversy came up and the high court ordered government to regulate medical devices. Government had no data or framework to regulate with and you need a lot to regulate. So at that time instead of passing a correct comprehensive law, what government did, they chose the route of notifying 10 devices as drugs under D&C without understanding what they are doing. That is how we have landed up in this mess.

(Interview data)

The Drugs and Cosmetics Act 1940 is the major source of pharmaceutical regulations in India and applies to all products whether local or imported. The primary objective of the Drugs and Cosmetic Act is to ensure safe and effective healthcare by regulating the import, export, manufacture, distribution and sale of drugs, cosmetics, and conduct of clinical trials. The amended act now included jurisdiction over "devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the central government". The Indian government set up this amendment with two primary aims: first, to improve the accessibility

of safe and effective devices and second, to support local manufacturers by creating a regulatory framework for notified medical devices.

Soon it emerged that there were serious problems with regulation of medical devices under the Drugs and Cosmetics Act. Increasingly medical devices firms operating in India began to experience the inconsistent application of the current guidelines causing renewed confusion and delays. These problems resulted in part from multiple levels of government authority involved in enforcing the guidelines, as well as inconsistent interpretation and application of the regulatory guidelines by customs officials at the ports, state drug controllers, and officials within the CDSCO (the US trade report, 2010). Some respondents point out that the domestic and international device manufacturers were assured that these regulations would not be stringently enforced with acknowledgement from regulators about lack of clarity and absence of capability to manage an increasing number of applications. In practice, the regulation was implemented inconsistently, and with errors, by multiple authorities.

Some companies struggled to get licenses for products for more than 6-7 months even when they had been on the market for more than two decades and had received regulatory approval for their products from overseas regulators (Kamath, 2007). Several experts concluded that the regulatory framework and infrastructure designed to govern pharmaceutical and cosmetic products was totally inadequate for governing medical devices due to the nature of difference in products, their action in human body and packaging. For example, the concept of sterility differs in pharma-biotech products and medical devices. A drug has to be manufactured in 'clean room conditions' requiring certain kind of flooring, air-flow and energy requirement to minimize impurities. In contrast, medical devices can be sterilised at the point of use, even in the operating theatre and don't require the same production conditions. For instance, an orthopaedic surgeon orders different sizes of implants from the company and at the time of surgery sterilises only those which fit patients. A head of Indian diagnostic company suggests,

The main pain point for medical device sector is that it is clubbed with pharma sector and treated like that. There is this fundamental issue. We went to the government, lobbying that medical device sector should be treated as a separate sector. It should not be a part of D&C act. And that's the reason why you find a lot of confusion.

(Interview data)

In the amended law, there was no regulatory mechanism for certification, quality assurance and post-marketing surveillance of imported and locally made medical devices except for the notified devices and diagnostics. Many of these devices are sterilised using various techniques, the efficacy of which need to be validated and current regulation fails to do so. These problems started to affect the availability of medical devices. Increasing pressure from industry association and complaints from patient groups forced the Indian government to act to improve the regulatory situation. That led to the drafting of the new amendment in 2007 aimed at improving medical device regulation and setting up a centralised regulatory authority. Soon this legislation ran into trouble due to lack of expertise and understanding within the government. An official with industry association highlights it as a key issue,

In the government, expertise to deal with the medical devices is not there. So if you look at the DCGI, their inspectors are basically pharma inspectors. They don't have the expertise on the medical device technology. Whatever rules they apply for drugs, they are applying for devices. But the entire principle is different. It's a completely a

different ball game. You are talking about pricing, you talk about barcoding and so on. All regulations that are in place for drugs, now they are applying for devices.
(Interview data)

During this period, the Department of Science and Technology (DST) and Ministry of Health, Family and Welfare (MoHFW) put forward two independent proposals, with DST suggesting the Medical Devices Safety Bill, 2008, as a comprehensive regulatory framework for medical devices and MoHFW arguing for establishment of a Central Drugs Authority (CDA) covering all regulated healthcare technology products. An official with industry association comments,

So there are two choices; Medical Devices Safety Bill which can get reactivated and this, in which within the drug authority a separate medical device regulation.
(Interview data)

Both these proposals shared two common objectives: a regulatory regime that distinguishes between pharmaceuticals and devices and adequate powers to ensure standards, efficacy, safety and availability of medical devices manufactured or marketed in the country. But they differed in the proposed governance structure required to achieve that. The MoHFW proposal had the CDA structure resembling the regulatory model used by the USFDA; a central body responsible for regulation, licensing, surveillance and monitoring of medical products and the uniform implementation of laws pertaining to medical devices within the country. It would collect fees for permission to conduct clinical trials for drugs, devices and cosmetics. The CDA would classify devices, notify standards and guidelines from time to time, provide a mechanism for conformity assessment using direct or third party notified bodies and stipulate the procedure and guidelines for testing laboratories. In contrast, the DST proposal suggested the adoption of a more de-centralised structure based on the governance framework adopted by the EMA. These differences led the Indian government to form a parliamentary committee in 2008, which came up with an alternative approach. The committee suggested amending Drugs and Cosmetic Act of 2007 to facilitate the formation of a financially self-sustaining regulatory body using the existing structure (DCGI/CDSCO) to handle the administration of medical devices regulation without creating a big, new infrastructure or encroaching on many of the responsibilities of other existing bodies. Based on the belief that it is not feasible to remove existing institutions, the committee recommended against establishing the CDA at this stage (interview data).

The parliamentary committee brought the focus back on the Mashelkar committee report by supporting one of its recommendation of restructuring, strengthening and modernizing the existing CDSCO under the MoHFW that will oversee a centralized licensing system and maintained a network of offices at the zonal and sub-zonal levels. Although all three proposals were unanimous about the inadequacy of the existing regulatory systems, they all differed on the governance system that should be adopted. The Parliamentary committee did note the delay in achieving appropriate regulation and linked it in part to the clashes and differences in approaches by the DST and the MoHFW. Prof. Valiathan points out,

The Indian Medical Regulatory Authority (IMDRA) proposed by a Government Committee would have been optimal. Thanks to a turf war in the Government, it has been substituted by a Committee under the DCGA (Drug Controller General of India). It is too highly centralised and too bureaucratic to promote R&D and industrial activity in relation to medical devices and instrumentation. Neither has become an Act yet.

(Interview data)

The Parliamentary Report involved more than one year of studies, consultation and negotiation with different stakeholders such as industry association, civil society organisations and industry experts (the US Trade Report, 2010). By 2008 the Federation of Indian Chambers of Commerce and Industry (FICCI), one of India's leading industry associations, took up this issue and emerged as a focal point for framing the regulations of medical devices. FICCI along with AdvaMed and medical device firms (local, importers and MNCs) started to work closely with the CDSCO and MoHFW to devise appropriate regulations that can aid access to medical devices, promote local production and streamlined the regulatory process towards global harmonisation. In late 2008, the Parliamentary Committee report was presented in the upper house of the Indian parliament and in December 2008 the MoHFW renewed re-drafting of the legislation as per the Parliamentary Committee's recommendations. During this period, medical devices manufactured and imported in India continued to be monitored under a wrong and confusing regulatory structure.

It became apparent that those regulations specific to the India medical device industry are somewhat limited and lacked clarity and transparency, while low internal quality standards contributed to wide quality variances among products on the market. One leading diagnostic device manufacturer reflects,

Lack of regulation was one big barrier and one of the worst things to happen. Now that regulation has come in, they have come in only for some spectrum of products. But these are also not correct regulation and thereby wrongly implemented by the government. So I don't know what is worst; not having regulation or having inappropriate regulation. That is a completely erroneous thing to do.

(Interview data)

The absence of clear regulations and inconsistent interpretation and application of the regulatory guidelines by multiple levels of government created a prolonged and cumbersome regulatory pathway for medical devices in India.

Furthermore, this lack of appropriate regulatory oversight has resulted in the industry populated by spurious operators and counterfeit traders who used scrap material as raw material or import goods of uneven quality from overseas manufacturers. Many small trading companies importing unregulated products from China, Korea and Taiwan at a very low rate, even lower than Indian firms' production cost mushroomed in the country. The market is flooded with non-standard look-like counterfeit products, which are sold at very low prices. Many of medical devices are implanted into the human body for critical care. Implanting a poor quality or defective device can cost the life of the patient and therefore require minimum standards and some control on prices. This lack of monitoring in India could have serious consequences for poor patients' healthcare, as they were main recipients of cheap counterfeit and unsafe medical devices. The managing director at an orthopaedic implant firm points out,

Due to lack of appropriate regulations, I will say almost all manufacturers chose to use non-certified raw material and focused on low-cost technologies. Few have bothered to set up quality checking units or invested in design & development facilities. There is no motivation, no innovation.

(Interview data)

Analysis of this short period of reactive and inappropriate regulation for medical devices has shown that it continued to place patients in India at risk. Without appropriate regulation, Indian firms lacked the incentive to produce and sell higher quality devices. This, in turn, has contributed to a lack of development of critical innovation ecosystem for advancing medical device production in India. It is a major weakness in Indian technology and innovation policy.

5.3 Phase III: New Medical Device Regulation bill: Towards a divergence from drug regulations (2009 to 2018)

Eventually, the Indian government realised the need for recognising medical devices as a distinct category in the healthcare industries and in 2009 introduced a chapter on medical devices in Drugs and Cosmetics Act. Under the amended Drugs and Cosmetics Act, regulatory control began to be observed at manufacturer, hospitals and market level and the CDSCO and DCGI in the MoHFW were nominated as central bodies involved in the governance of drugs and medical devices in the India. To facilitate administration of device regulation, the CDSCO established two different units: Device cell and Diagnostic cell, responsible for the oversight of medical devices and diagnostic firms. The CDSCO was designated as the responsible authority for the dissemination of information on registered medical devices, licensed distributors, and compliance. It adopted a divisional structure; with the central division, responsible for drafting of device standards and regulations of clinical research while state divisions were put in charge of recalls and licensing of manufacturing sites. Along with the CDSCO, the Bureau of Indian Standards (BIS) continues to regulate few other low technology devices. The imported high technology devices, approved by the country of the origin or by the US FDA, are permitted for marketing in India. The importers of medical devices can use their approvals in the US, Canada, Europe, Australia or Japan to register their medical devices in India. In parallel, the CDSCO also devised autonomous Good Manufacturing Practices (GMP) regulations for production of medical devices in India. These guidelines were separate from pharmaceutical sector and under the new rules, the manufacturer was required to comply with GMP to gain approvals. This amendment provided key guidelines for local manufacturers on standards required for authorisation of the medical devices and thereby an opportunity to develop devices that can compete with MNC products.

These provisions again proved inadequate. In 2009, different industry associations intensified their effort and in response, the Indian government formed the Indian Medical Device Regulatory Review Group (IMDRV) as a forum for the industry, the regulators including the conformity assessment bodies, the testing institutions, and consumer groups to bring around overdue reform. AiMED along with other industry associations made strong representation to the IMDRV group and that led to the framing of specific regulations for medical device industries in 2012. The Drugs and Cosmetics (Amendment) Bill 2013 was introduced to the upper house of parliament in 2014. This draft provision laid out are largely in line with standard international practices developed by the International Medical Device Regulators Forum (IMDRF). This new legislation is expected to bring all medical devices sold in India under the purview of the government agency charged with regulating medical devices: the Central Licensing Approval Authority (CLAA) under the CDSCO. However, there still remains an issue of the appropriateness of these provisions for local contexts and their impact on supporting local innovations. For example, new bill defines adulterated device as any device that is composed of in any measure “rusted or corroded or filthy or putrid or decomposed substance”, packed under unsanitary conditions that would make it hazardous to someone’s health, contains toxic substances, and so on” and puts total responsibility of

‘adulterated device’ on manufacturer. However, the head of medical device industry association points out that device can become contaminated at point of use,

So even if a user stores a device improperly, it's the manufacturers who will be held liable. That's not all. The bill talks about minimum standards for medical devices but doesn't define what these standards are. These devices are pieces of science and engineering. You can measure the efficacy of drugs, but not of a medical device. The government should measure their performance. Drugs and medical devices are two separate things. You can't measure them with the same indicators
(Nagarajan, 2013)

The Indian government is continued to grapple with establishing a medical regulatory regime that can distinguish between devices and drugs but struggling to set up a governance structure that will satisfy different stakeholders. The head of Indian industry association comment,

FICCI was first association to take the proposal to the government that devices and drugs need a different formulation. We have been going back and forth. The government says the new bill is going to take time. But new bill doesn't include what we are suggesting; that it should include a separate chapter for devices. After all, we worked very hard with the health ministry to come up with the rules. But that is stuck in parliament, which is beyond our control.

(Interview data/2015)

Further, new medical technologies and global markets require continuous reform of the respective regulatory framework and increasingly tailor-made and product-specific regulation. This clearly indicates that the Indian regulator needs to set up a different autonomous department that can work with companies, clinicians and hospitals. A senior official of a leading industry association suggests,

We are working with the department of pharmaceuticals to create a separate division for medical devices and have a separate regulator. That way you can start building expertise. Existing situation of a regulator for devices working under the DCGI is not the best way forward. You need to have a third party, standalone regulator like you have for telecom, insurance and finance sector. It's important that regulator should be independent and should be equivalent to secretary of India, reporting directly to minister rather than a joint secretary.

(Interview data/2015)

In 2017 the Indian health ministry separated regulatory frameworks for manufacturing of drugs and devices by issuing Medical Device Rules, 2017. Medical devices have been divided into four categories based on their risk type – Class A, B, C and D, where A and B covers low-risk devices such as diagnostic equipment and C and D cover high-risk devices such as implantable devices. It was notified that the central agencies will be involved in approving devices in C and D category. These rules were influenced by the international standards and strictly conform with Global Harmonisation Task Force (GHTF) framework further highlighting the influence of global harmonisation agreements. Building on this, the new Indian medical device regulations came into force on 1st January 2018.

In this phase, some improvements were made: industry associations were more assertive and government began to build a more responsive and appropriate regulatory environment but our

data suggest that weaknesses in regulation and technology policy for medical devices remain. This data on the evolution of medical device regulation highlight the conditions and processes that led to the emergence of ineffective medical device regulations in India. The different phases of regulatory evolution together had a significant impact on the development of local production capabilities as well as ensuring access to affordable devices to the local population.

6.0 Analysis and discussion

The evidence presented here reveals that long-standing communication gaps between the Indian medical device industry and the Indian government, between different government departments and knowledge gaps among policymakers in understanding needs of the medical device sector have contributed negatively to the development of effective medical device regulation in India. In turn, this regulatory environment has allowed foreign-owned MNCs and their expensive products to dominate the Indian market which has had a significant negative impact on the development of local technological capabilities and availability of affordable medical devices in India

Collective action: Weak government- industry- civils society organisation linkages

Unlike countries such as the US, Japan and the EU, India consistently neglected to decouple regulation for medical devices from pharmaceuticals. Following independence, successive Indian governments effectively supported the growth of the Indian pharmaceutical industry through the Patent Act of 1970 along with protections against imports and sustained investments in India's pharma based S&T infrastructure, particularly the building of research institutes and the training of an S&T workforce. This support for pharma, and to an extent biotech, never transferred to the burgeoning Indian medical device industry. An overarching reason for this was a significant and long-standing lack of substantive linkages between the Indian government and the Indian medical device industry. In developing countries, the importance of knowledge flows between government and industry through the auspices of industry associations, particularly in the transfer of global knowledge on standards and practices to the national and local level is well established (Papaioannou et al., 2016). In India, the long-standing absence of a strong industry-specific association representing the interests of the Indian medical device industry proved to be a major barrier, preventing institutionalised communication and exchange of ideas between government and industry. An official with an industry association suggests that competing interests of domestic industry with MNC proved to be a major hindrance,

When you say 70% of the business is done by MNCs who do not have domestic manufacturing, but import, there is a very strong need to sustain those imports. Thereby, to have an industry body which will talk in one voice to encourage domestic industry is not a reality today. It will not happen. In the med-tech industry as opposed to the car industry, it becomes a little difficult to convince why you should stop free imports [when a viable domestic industry does not exist].

(Interview data, 2015)

This gap in communication was filled by civil society and the active intervention of the judiciary. This ceding of political space forced governments towards framing of the regulation without requisite industry expertise and understanding, leading to the adoption of the inappropriate regulation. While more recent efforts at forging more appropriate regulation have seen the involvement of both domestic and international industry associations, building

government expertise in medical devices has proven challenging, although government reception to the industry has improved. A head of a leading Indian orthopaedic company suggests,

In the beginning, it was a chain of knee-jerk reactions. Now of course government authorities understand what is needed but it's been five years since the wrong regulation. We have been involved in making them understand the so the central office understands what is needed but now we are waiting for the amendment of the drugs act in which they will define medical devices independently and appropriately.
(Interview data, 2015)

As an example of more recent efforts, the U.S. medical device trade association AdvaMed is working alongside the American Chamber of Commerce (AMCHAM), the Confederation of Indian Industry (CII), and FICCI in providing the Indian government a considerable amount of information and suggestions on ways to improve effectiveness of proposed medical device regulations. For example, these associations are working in conjunction to lobby the Indian government to harmonize India's medical device regulations to be consistent with established regulatory systems of the advanced countries.

Policy fragmentation within government

In addition to the Indian government's long-standing focus on pharmaceuticals to the exclusion of medical devices as a distinct healthcare industry, a lack of communication and policy coherence among different departments within the government and their areas of jurisdiction have compounded significant complications in developing an appropriate regulation. A head of leading industry association points out,

So today we are saying simplify the regulation, why do we need to report to five ministries and none of these ministries talks to each other, they are all asynchronous in these ministries... the whole thing is they are just not working in unison and nobody knows all the aspects when they are making decisions on a certain subject.
(Interview data, 2015)

Post-2005, the legislation for governing medical devices has undergone a number of different drafting stages during which time the MoHFW and DST repeatedly clashed on the governance mechanism and debated a number of issues with limited results (interview data). Up to certain level, this policy fragmentation is expected, but these divisions and knowledge gaps between departments have resulted in a situation where the governance process and subsequent regulation of medical devices are still highly ambiguous and uncertain. Evidence points to continued knowledge gap among different policymakers on the precise regulatory needs of medical device industry. Expressing frustrations at the pace of changes, an entrepreneur of an emerging diagnostic firm suggests,

We are trying to create awareness but it's not coming easily. It takes time to move things which have been settled for so many years. We were so small that we became invisible for the government.

(Interview data)

This evolving regulatory framework has and continues to have the significant impact on the development of the Indian medical device industry. It has severely handicapped local manufacturers by hindering predictable access to market and limiting the growth of a collaborative network of firms and research institutes. This, in turn, has allowed and

reinforced an Indian medical device market dominated by MNCs and their expensive products and the subsequent proliferation of counterfeit devices.

Handicapping both local manufacturers and innovation ecosystems

The evolving regulatory process created a significant hurdle for the local manufacturer to develop products locally and enter the domestic as well as international markets. A regulatory approval process for high-tech products was highly ad-hoc and in many cases, the local innovators had no idea whose approval they should take to launch a product. A head of orthopaedic company suggests,

Doing the right things is not incentivised and that's why the image of the country worsens. Reality is, if well-regulated industry exists, then all those who are doing counterfeit work today, will not be doing it. They would be doing right things and then there will be competition amongst right companies. Between them, these companies can do whatever is appropriate, those who can manage to create innovations or manage to have cost efficiency to succeed. But then this country will get a fantastic image that you get good quality products in this country. It doesn't matter which company you go to. That is where regulation and good regulation plays a key role, in changing the face of the industry.

(Interview data)

The struggle for domestic companies is well evident in the example of Sri Chitra Research Institute. Murthy (2004) points out that from 1994 to 2004 more than 11,000 valve procedures were done per year in India, but only 1,000 valves developed by the Sri Chitra Research Institute were used even though they cost less than 50% of the average of imported valves. The Indian clinical community is averse to using devices of the local manufacturers because of uncertain standards and lack of quality assurance. A leading manufacturer comments on attitude of Indian clinicians,

It is certainly a barrier but it is not necessarily ill-founded. It's a combination of events. If we have to say that users should not have this mindset and we must also have to develop the impeccable domestic industry. So domestic industry might be comprised of few companies but whatever comes out of those companies is top-class. The day you do this then the mindset will change. But if you have a situation where there are a huge number of companies producing inappropriate products and a few companies that are doing good things. I have dealt with best companies in the world. They are not without problems; they have problems from quality to service delivery. I have seen that happened. But to the larger extent, they do it in right way, because it has a certain cultural thing, their strict regulatory control and then the image of that country is different.

(Interview data)

Furthermore, innovation processes in the medical device sector require an interactive ecosystem of institutions and firms working closely with practitioners and users. Majority of Indian medical device firms were engaged in the low technology products and lacked any motivation for collaboration, as there were no incentives for innovation or protection to prevent counterfeit manufacturers from encroaching the marketplace. Some success stories emerged out of effort from entrepreneurs but these collaborations never became institutionalised. An orthopaedic equipment manufacturer points out,

Over and above that regulation plays an important role so that the innovation is managed and well controlled. That is how it works. Without industry and clinician collaboration you can't validate what you are doing. However, I am not saying it is not there. I am only saying it is very limited. For instance, we are working on a special limb salvage solution. For this type of solution, we have worked with Tata Memorial to develop this. This type of things needs to be done. All I am saying that there are examples but they are few and far in between as far as India is concerned.

(Interview data)

In this way, the clear lack of protection and motivation for innovation has so far prevented the creation of an innovation ecosystem that links medical device firms, research institutes and leading hospitals. Such an ecosystem might not only help facilitate the technological capacities of Indian firms but for doing so, might also link Indian firms to foreign-based MNCs and other sources of global knowledge and capabilities.

Monopoly rent: MNC dominate domestic market

Without proper regulation, the local Indian medical device manufacturers have struggled to gain acceptance for their products in the domestic market and often fared poorly against products from foreign-owned MNCs, which were approved by the western regulators and backed by huge amounts of clinical trials data. This absence of local competition and total dependence on imports gave MNCs monopoly power over the Indian domestic market. MNCs sold their products in the Indian market without really taking into consideration of production cost or purchasing power of local populations, as there were no local competitors creating pressure to reduce prices and no regulation to monitor their profit margins. Thus, the total lack of regulation created a skewed market in favour of MNCs, allowing these companies to charge 'monopoly rent'. A leading cardiac surgeon comments on domination of MNCs firm on the Indian medical device industry,

We are compelled to import 90% of high-end instruments, devices, etc for our hospitals at high cost and replace them every 3-5 years at still higher cost. This pushes up the cost of specialised care in cardiology, neurology, etc and makes them inaccessible to the majority of Indians. They play no role in the development of local industry and their aggressive marketing of products has inhibited indigenous R&D and industry.

(Interview data)

This skewed market created immense problems for securing access of affordable devices for the local population. Further, MNCs were primarily involved in the distribution of medical devices and seek to enter the domestic market either by employing local agents as distributors or setting up sales and distribution presence. A cardiac device manufacturer comments,

The fact that there is no MNC investment in manufacturing here except for a few, which is recent and very small, says something. Out of what MNCs do in India as a way to sell, it's a small component they look for local development and manufacturing. The reason why you don't see widespread investment is itself enough explanation to make people understand that unless India takes a global view, it's not a suitable location for manufacturing and development from the perspective of being a conducive environment. Which is where we come back to regulation.

(Interview data)

In sum, the long-standing lack of appropriate medical device regulation in India has led to a massive gap in technological and industrial development in a crucial sector for health. It not only discouraged investment in the medical device industry by the Indian government and Indian firms, but has also de-incentivised foreign-owned MNCs from investing in the manufacturing of medical devices in India – a potentially important pathway toward building domestic innovation ecosystems for medical devices in India.

7.0 Conclusion

This study is the first to provide an in-depth analysis of the conditions and processes involved in the evolution of medical device regulations in a developing country, their impact on the local market, firms and popular access to devices. It does this by studying the evolution of medical device regulation in India. It shows that the lack of regulation has had a significant negative impact on the development of local technological capabilities and the availability of affordable medical devices in India.

The evidence presented here reveals the existence of communication gaps between industry and government, gaps between different government departments and also gaps in understanding the needs of the medical device sector among policymakers as a key challenge to the development of effective regulation in India. Further, different government departments work with their own policy objectives which adds further fragmentation and complexity to the process. In case of the Indian medical device regulations disagreements were concerned not only with the content of policies and who should be in charge but also with how policies should be made, who should be involved and how much regulation there should be. In short, stakeholders should ‘mind the gap’ and make concerted efforts to bridge these ‘gaps’ to avoid a regulation quagmire and arrested development.

Evidence from this research also shows that this gap can be bridged by stakeholders such as national and international industry associations, consultants and experts (Altenstetter, 2012). As such, substantive knowledge exchange between industry and government helps policymakers to understand the regulatory needs of the evolving technology and set up appropriate policies. This suggests that the state, even though the most important planning institution, rarely holds all the necessary expertise, bringing into sharp focus the role and contribution of other institutional actors such as, again industry associations, along with civil society organisations and the judiciary. These different actors compete, contest and, at times, collaborate with each other to achieve policy outcomes that suit their objectives. This is critical aspect of the policy development that policy makers need to grasp as dynamics of science and technology unfold in India. It is critical that the contestations are embraced as integral process of policy development. Different coalitions emerged as policy moved from one stage to another with conflict and contestation forming key mechanisms for institutional change. This research reinforces that regulation policy is inherently political and often a complicated process with conflict and negotiation forming essence of the process. The embeddedness of this policy process in Indian political and social life is revealing and important for any discussion about what appropriate policy responses might be to the regulatory dilemmas presented by healthcare sector within the developing country context.

Similar to Scoones (2003:3) reflections on regulation in the agri-biotechnology sector, this research "raises a number of different perspectives, both challenging, and importantly, broadening, the framing of the debate from one of a narrow, "back-end" concern with risks and technology impacts to a much wider "front end" discussion about inclusive development". It indicates that the stakes involved in the steering of life sciences industries are very high,

with the involved actors needing to have a good understanding of technology – regulation interactions and their implications for affordable healthcare. As the Indian evidence suggests that, while regulation can create more equitable playing fields, which can be vital for harnessing innovation, not just any regulation will do. We show the importance of smart regulation for technology and industry policy towards more inclusive healthcare. Despite the international pressure of uniformity and harmonisation in regulatory policy, this paper shows the fallacy of that approach by highlighting the significance of local contexts and how there clearly can be no one-size-fits-all solution. This indicates that the developing countries should focus on creating regulations that will ensure safety, efficacy and quality parameters that match consumer expectations and are suitable to the local context.

8. References

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Mind the gap: Investigating the conditions and processes involved in influencing the development of medical device regulation in India**Highlights**

This article represents our first publication of completely new data from fieldwork, which has been carried out over the last three years. There are three novel and unique contributions that we would like to make to the field through this paper.

First, this study is the first to provide an in-depth analysis of the conditions and processes involved in the evolution of medical device regulation in a developing country and its impact on the local market, firms and access. Medical device regulations in developing countries have remained a neglected area in the Development Studies (DS), Science and Technology Studies (STS) and Innovation System (IS) literature. This research fills that gap.

Secondly, and following from this first point, this paper unpacks the conditions and process associated with the development of medical device regulations in India and argues that gaps in policy makers' understanding of the underlying technology in medical device sector, together with communication gaps between government-industry and among different government departments led to ineffective regulation. In turn, lack of appropriate regulation severely hampered the development of technological capabilities by local manufacturers, skewed markets in favour of MNCs and ultimately, had a damaging impact on inclusive healthcare in India.

Third, it also shows that contestation and conflict act as key mechanisms through which different stakeholders influence, enable and/or disable institutional change.

These findings have a significant impact for other developing countries which are struggling with development of medical device regulation appropriate to local conditions.